

SpineSmith Cequence Anterior Cervical Plate System

510(k) Summary of Safety and Effectiveness

JUL 14 2008

SUBMITTED BY SpineSmith Partners, LP
8140 N. Mopac, Bldg II, Suite 120
Austin, TX 78759

**ESTABLISHMENT
REGISTRATION NUMBER** 3006404071

CONTACT PERSON Robert Jones
Vice President, Research and Development
Phone: 512-206-0770
Fax: 512-637-6750
Email: rjones@spinesmithusa.com

SUBMISSION PREPARED BY Lisa Peterson
Kaedon Consulting, LLC
Phone: 512-507-0746

DATE PREPARED April 18, 2008

CLASSIFICATION KWQ 888.3060- Spinal Intervertebral Body Fixation
Orthosis

COMMON NAME Spinal Fixation System

PROPRIETARY NAME SpineSmith Cequence Anterior Cervical Plate System

**SUBSTANTIAL
EQUIVALENCE** The SpineSmith Cequence System was determined to be
substantially equivalent to the predicate device.

DEVICE DESCRIPTION

The Cequence anterior cervical plates are preassembled and are offered in both a constrained and semi-constrained configuration. Cequence consists of four (4) primary components: 1) anterior plate, 2) self-tapping bone screws, 3) locking screws and 4) locking plate.

INDICATIONS:

The SpineSmith Cequence Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine at one level between C2-C7 for the following indications:

- Degenerative disc disease [DDD] – defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spinal Stenosis
- Tumors
- Trauma (i.e. fracture)

MECHANICAL TEST DATA

Mechanical test results demonstrate that the proposed Cequence System is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spine Smith Partners, L.P.
% Mr. Robert Jones
8140 North Mopac
Building II, Suite 120
Austin, TX 78759

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Rc: K081132
Trade/Device Name: SpineSmith Partners, LP Cequence Anterior
Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: June 27, 2008
Received: June 30, 2008

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: SpineSmith Partners, LP **Cequence Anterior Cervical Plate System**

Indications for Use:

The SpineSmith Cequence Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine at one level between C2-C7 for the following indications:

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- Spinal Stenosis
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- Trauma (i.e. fracture)

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K081132